510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY ASSAY AND
INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k073030

B. Purpose for Submission:
New device

C. Measurand:
Whole blood glucose

D. Type of Test:
Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:
Andon Health Co., Ltd.

F. Proprietary and Established Names:
AG-605 Blood Glucose Monitoring System
AG-606 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1345, Glucose Test System
2. Classification:
   Class II
3. Product code:
   NBW, CGA
4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
   See Indications for use.
2. Indication(s) for use:
   AG-605 & AG-606 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger only. Testing is done outside the body (In Vitro diagnostic use). It is indicated for both lay use by people with diabetes and in a clinical setting by health care professionals, as an aid to monitoring levels in Diabetes Mellitus. Not for use on neonates.
3. Special conditions for use statements):
   - Not for neonatal use
   - Not for screening or diagnosis of diabetes mellitus
   - Not for patients who are dehydrated, in shock, critically ill, or in a hyperosmolar state
4. Special instrument requirements:
   AG-605 Blood Glucose Monitoring System or AG-606 Blood Glucose Monitoring System

I. Device Description:

The AG-605 and AG-606 Blood Glucose Monitoring System is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 5 seconds. The control solutions available are used to test the performance of the device. The AG-605 and AG-606 use the same technological characteristics for testing but differing in the following ways:

Model	AG-605	AG-606
Principle		
Machine size	112mm (L) x50mm(W) x22mm(H)	82 mm(L)x59mm(W) x20mm(H)
Key-press	4	2
Memory capacity	160 results	350 results
Test time	5s	5s
Display the average of test result		Can display the average of test results of 14 days or 30 days
Display the temperature in CTL mode		Can display the temperature in CTL mode

As the devices both use the same testing technology, only the AG-605 was used for performance testing.

J. Substantial Equivalence Information:

1. Predicate device namefe):
   LifeScan Inc., One Touch Ultra Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
   k024194
3. Comparison with predicate:

Similarities		
Item	**Devices**	**Predicate**
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Test Range	20-600mg/dL	20-600mg/dL
Volume Required	1.0 uL	1.0 uL
Hematocrit Range	30-55%	30-55%
Test Time	5 seconds	5 seconds

Differences		
Item	**Device**	Predicate
Temperature Range	10-40°C	6-44°C

K. Standard/Guidance Document Referenced (if applicable):

- ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

L. Test Principle:

Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Testing was done using whole blood samples spiked with five different glucose concentrations, three different reagent lots, and 10 different AG-605 blood glucose meters. Each combination of multivariate factors was evaluated using 10 measurements. Day-to-day precision was evaluated using three glucose control solutions with concentration levels, low, normal, and high. The day-to-day precision was evaluated over a ten-day period using three different reagent lots. The summary of test results is presented below.

Repeatability (within-day precision):

Sample level (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	45	1.8	3.89
51-110	100	100.5	2.9	2.85
111-150	100	134	3.6	2.76
151-250	100	215	5.8	2.75
251-400	100	355	7.2	2.11

Reproducibility (day-to- lay precision)

Sample level (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Low	100	89.4	3	3.34
Medium	100	133	4.3	3.26
High	100	334	8	2.45

b. Linearity/assay reportable range:

Testing was done with 11 spiked whole blood samples over the range of 22-596 mg/dL (as measured by the reference method), compared with the values generated from YSI-2300 analyzer. A regression analysis showed linearity of AG-605 blood glucose monitoring systems with a linear regression of $y = 1.0388x - 3.4407$ and an $r^2 = 0.9971$.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Open vial stability was tested using three levels of control solution every day over a 3 month period. The sponsor's acceptance criteria for the control solution (<±15 mg/dL for less than 100 mg/dL glucose and < ±15% bias for samples greater than or equal to 100 mg/dL glucose) was met which supported an open vial stability claim of 3 months.

The controls are traceable to a laboratory reference method.

d. Detection limit:

The measuring range of the system is 20 - 600 mg/dL. This range was verified by the linearity study (above section M.1.b.).

e. Analytical specificity:

Interfering substances were dissolved in venous blood samples at several concentrations each, and divided into three aliquots and spiked to nominal glucose concentrations of 70,120, and 230 mg/dL. These samples were tested against control samples which had a blank solvent added at the same volume as the interferent. Samples were tested 10 times and the percent difference of the interfering samples was calculated and compared to the control samples. The following substances were tested.

Exogenous Substances	Reference Range (mg/dL)	Concentration Showing No Interference (mg/dL)
Acetaminophen	1-2	5
Ascorbic Acid	0.8-1.2	10
Ephedrine	2	50
Ibuprofen	0.5-4.2	50
L- Dopa	0.3-10	5
Methyl Dopa	0.1-0.5	10
Dopamine	NA	10
Salicylate	15-30	50
Tetracycline	0.4-4	2.5
Tolazamide	2.5	10
Tolbutamide	5.3-10	50

Endogenous Substances	Reference Range (mg/dL)	Concentration Showing No Interference (mg/dL)
Bilirubin	1.2	5
Cholesterol	<250	500
Creatinine	1.5	20
Hemoglobin	~15g/dL	50 g/dL
Triglyceride	<190	500
Uric Acid	7	10

Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal therapeutic concentrations) do not significantly affect results. The sponsor notes in the labeling that abnormally high concentrations in blood may cause inaccurately high results. Triglyceride of up to 400 mg/dL (4.5 mmol/L) do not affect the result. When triglyceride was tested at 500 mg/dL in a sample with a glucose concentration of 400 mg/dL, it showed a bias of 16%, however all other glucose concentrations tested showed bias of <±11%. The labeling will indicate that triglyceride concentrations of 400 mg/dL and below do not affect results. All other compounds tested above showed biases within the sponsors acceptance criteria of a bias <±15%.

The effect of hematocrit levels of 20 - 70% was tested on whole blood samples spiked with six hematocrit levels at glucose values (7 levels) distributed within the measuring range (25 - 492 mg/dL) of the device. The values generated were compared with the glucose values from YSI-2300 analyzer. The regression analysis for each hematocrit level is summarized in the table below. The results generated by the device are comparable to the values of YSI-2300 instrument at hematocrit levels between 20-60%. The sponsor will claim a hematocrit range of 30 to 55%.

Hematocrit %	Slope and Y-intercept	R
20	y= 0.957x+2.939	0.998
30	y= 0.966x+4.233	0.996
40	y= 0.967x+4.346	0.999
50	y=0.961x+4.496	0.999
60	y= 0.946x+5.469	0.999
70	y= 0.955x+8.053	0.996

An altitude study was performed with whole blood samples from 20 volunteers (glucose range: 68-157 mg/dL) and 3 control solutions at low (40 mg/dL), medium (110 mg/dL) and high (350 mg/dL) concentrations tested 20 times each. All the controls met the acceptability criterion of CV<5% for the control solutions measured at sea level and at an altitude of 10,000 feet. The data submitted support use of the device up to 10,000 feet.

Temperature and humidity studies were performed and showed that the meter can be used at temperature form 50°F to 104°F and at relative humidity ranging from 25% to 85%.

f. *Assay cut-off:*
Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Samples from 300 volunteers with glucose concentrations distributed over the range of 20 - 546 mg/dL were evaluated at three different hospitals. Each blood sample from the volunteers was divided in two, one was tested by YSI-2300 and the other was tested by AG-605 blood glucose meter. Percent distribution of the samples corresponding to the glucose concentration ranged as follows: 20-50 mg/dL -5.7%; 51-110 mg/dL - 32.7%; 111- 150 mg/dL - 19.3%; 151-250 mg/dL - 19.6%; 251- 400 mg/dL - 18.3%; and 401-600 mg/dL - 4.3%. To obtain the blood glucose concentrations less than 40 and more than 400 mg/dL, a pooled capillary whole blood specimen was spiked with the desired glucose levels. Based on data analysis, the device met the minimum system accuracy requirement established according to the ISO 15197 guidelines, which is 95% of the individual differences are within ±15mg/dL when glucose concentrations are less than 75mg/dL, and are within ±20% when glucose concentrations are >75mg/dL. In comparison with YSI-2300, all three sites showed regression correlation (r^2) values ranging between 0.981-0.992. Results for all three sites combined and for each AG-605 meter using strip AGS-600 are given below.

System accuracy results for glucose concentrations < 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
26/48 (54%)	45/48 (94%)	48/48(100%)

System accuracy results for glucose concentrations >75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
99/252 (39%)	194/252(77%)	233/252 (92%)	252/252(100%)

A usability test was performed by 50 volunteers and healthcare professionals respectively with glucose levels ranging from 58 to 369 mg/dL when measured by the healthcare professional. Each volunteer was offered one AG-605 blood glucose meter; three test strips (three different lots), one vial of control solution, one user manual, one lancing device and three lancets. After reviewing the materials, the user performed their own finger sticks and tested themselves using the blood glucose monitoring system. Immediately after the user's self-test, a second blood sample was collected and the healthcare professional tested it with the same blood glucose monitoring system. Comparing the two test results, it was determined that users can test by themselves correctly according to the instruction for use. Test results are summarized below.

Test result by the volunteers versus the healthcare professionals

Within ±lmg/dL	Within ±2mg/dL	Within ±3mg/dL	Within ±5mg/dL	Within ±10mg/dL
12/50(24%)	21/50(42%)	35/50(70%)	49/50(98%)	50/50(100%)

b. Matrix comparison:
Not applicable. Capillary whole blood is the only indicated matrix.

3. **Clinical studies:**
   a. Clinical Sensitivity:
   Not Applicable
   b. Clinical specificity:
   Not Applicable
   c. Other clinical supportive data (when a. and b. are not applicable):
   The sponsor provided a readability study that indicated that the user manual, test strip labeling, and control solution labeling is at an 8th grade reading level or below.

4. **Clinical cut-off:**
   Not Applicable

5. Expected values/Reference range:
The sponsor included the following expected values for glucose levels for people without diabetes in their strip labeling and user manual:

Less than 1 lOmg/dL (6.1mmol/L) before meals
Less than 140mg/dL (7.8mmol/L) two hours after meals

Reference: WHO: Definition and Diagnosis of Diabetes Mellitus and Intermediate Hyperglycemia (http://www.who.int/diabetes/publications/Definition%20and%20diagnosis%20of%20diabetes_new.pdf)

N. **Instrument Name:**
AG-605 Blood Glucose Monitoring System
AG-606 Blood Glucose Monitoring System

O. System Descriptions:
1. Modes of Operation:
   Each test strip is single use and must be replaced with a new strip for additional readings.
2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes __ X___ or No _____
3. Specimen Identification:
   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:
   This device is intended to be used with capillary whole blood from the finger only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.
5. Calibration:
   A code number is provided with each batch of test strips to calibrate the meter for that batch. The code number is associated with the meter by inserting a test strip and entering the code number to match that found on the test strip bottle. No further calibrations are required of the user.
6. Quality Control:
   The sponsor has three levels of controls available for this meter with one level coming with the kit and the other two levels being available through the distributor. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to a troubleshooting section (in the control test section) of the owner's manual to identify possible reasons control results may fall outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

None

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.